

Balloon dilatation of critical stenosis of the pulmonary valve in neonates

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Abstract

Percutaneous balloon dilatation was attempted in 15 consecutive neonates (mean age 7.3 (range 1-27) days and weight 3.2 (range 2.5-4.1) kg) with critical stenosis of the pulmonary valve. Dilatation was successful in 11 (73%) patients. The mean balloon to annulus ratio was 1.1 (range 0.6-1.77). The ratio of right ventricle to femoral artery systolic pressure decreased from a mean (1 SD) of 1.4 (0.32) before to 0.8 (0.24) after dilatation and the transvalvar gradient decreased from 81 (29.7) mm Hg before to 33 (27.7) mm Hg after dilatation. All four (27%) patients in whom dilatation was unsuccessful underwent surgical valvotomy. Complications of balloon dilatation occurred in three (20%) patients; these included retroperitoneal haematoma (one) and iliofemoral venous occlusion (two). In one (7%) patient severe hypoxia and hypotension developed when the valve was crossed with a guide wire and balloon catheter. Despite successful dilatation he died 7 days after the procedure. During a mean (1 SD) follow up of 2 (1.7) years, seven (64%) of the 11 patients remained free of important restenosis. One patient required repeat dilatation three weeks after the initial procedure. In three (27%) patients restenosis developed 4-9 months after dilatation and all three had surgical valvotomy. Of the four patients initially referred for surgery three required a second operation and one required balloon dilatation.

Percutaneous balloon dilatation gave effective relief of critical pulmonary stenosis in most neonates but complications and restenosis requiring surgery were common.

neonates with critical stenosis of the pulmonary valve,² but may be associated with more haemodynamic disturbances and may be less well tolerated, especially if the ductus arteriosus has closed. So far only short term results have been reported in small numbers of patients.^{7,8} We report our experience with 15 consecutive neonates with critical stenosis of the pulmonary valve in whom this treatment was attempted.

Patients and methods

PATIENTS

Since November 1983 we have attempted percutaneous balloon dilatation of the pulmonary valve in 15 consecutive neonates with critical stenosis of the pulmonary valve. The average age at cardiac catheterisation was 7.3 days (median age 4 days, range 1-27) and mean weight 3.2 (range 2.5-4.1) kg. The diagnosis was established antenatally by cross sectional echocardiography in five (33%) patients. In all the clinical diagnosis was confirmed by postnatal cross sectional and Doppler echocardiography. All patients were cyanosed and 13 were treated with prostaglandin E₂ infusion before catheterisation.

TECHNIQUE OF CARDIAC CATHETERISATION AND BALLOON DILATATION

Cardiac catheterisation and balloon dilatation were performed under general anaesthesia in eight patients and under local anaesthesia with intravenous ketamine in the remainder. A full preliminary diagnostic catheterisation was performed via a percutaneous femoral vein puncture. Arterial pressure was monitored continuously by either femoral, umbilical, radial, or brachial arterial lines. A right ventricular angiogram was performed and recorded in the anteroposterior or the left lateral projections or both. The diameter of the pulmonary valve annulus was then measured from the lateral cineangiogram at the level of the attachment of the valve leaflets. We corrected this measurement for the magnification of the angiogram by reference to the external diameter of the angiography catheter. Then we selected a balloon catheter that was appropriate for the corrected annulus size. During the initial period of the study we used balloons with a diameter equal to or somewhat larger than the annulus. Subsequently we used balloons 20%-40% bigger than the annulus. The ductus arteriosus was open in 13 patients, though it was only small in five of them.

Since successful balloon dilatation of the stenotic pulmonary valve was first described,¹ several studies have shown its safety and efficacy in infants and children.²⁻⁴ When large enough balloons were used for dilatation, acceptable reductions in transvalvar gradients were obtained. The results compared favourably with those of valvotomy.^{5,6} In these age groups most centres prefer balloon dilatation for the treatment of valvar pulmonary stenosis.

Balloon dilatation is also possible in neo-

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The pulmonary valve was crossed by standard 0.020 inch (two patients) or 0.018 inch (four patients) guide wires (William Cook Europe) and 4 or 5 French multipurpose end hole catheters. In the latter half of the study period when it was not possible to cross the valve with the standard guide wires we used a "super floppy" or "steerable" exchange guide wire (Schneider Shiley UK, 0.018–0.020 inch diameter) in five patients before abandoning the attempt. Once the end hole catheter was across the valve we used it to pass an exchange wire of a diameter appropriate for the balloon catheter. In seven patients the guide wire was positioned in the peripheral left pulmonary artery, in one patient in the right pulmonary artery, and in three through the ductus arteriosus. In one patient a guide wire (standard 0.018 inch wire) could not be passed to a stable position. In three patients with angiographically dysplastic valves the pulmonary valve was not crossed (in two with standard guide wires and in one patient with additional Ebstein's anomaly a "steerable" wire was used).

When the guide wire was in a satisfactory position the end hole catheter and venous sheath were removed and the balloon dilatation catheter was passed over the wire (Schneider Shiley UK, Mansfield Scientific, and Meadox Surgimed USA). We used still frames from the angiograms as a guide to placing the balloon catheter with its mid-point across the valve. The balloon was then inflated with dilute contrast medium until the constriction caused by the stenosed pulmonary valve disappeared. The inflation-deflation cycle lasted 15–20 s. After balloon dilatation the balloon catheter was exchanged for a Goodale-Lubin catheter to measure the transvalve withdrawal gradient and right ventricular pressure. Repeat angiography was not routinely performed. The mean length of the procedure was 2.4 (range 1.1–3.9) hours. The mean duration of x ray screening was 34.8 minutes (range 10–57 minutes). In patients in whom dilatation was successful, the mean (1 SD) annulus diameter was 7.4 (1.6) mm. The diameter of the balloons used ranged from 3 to 10 mm. The maximum balloon to annulus ratios ranged from 0.63 to 1.77 (mean 1.1 (0.28)).

BALLOON DILATATION IN STEPS

Only one balloon was used in seven patients. In the last four patients, because it was impossible to pass a 5 French catheter through the valve without causing hypotension and hypoxia, preliminary dilatation was performed with 3–5 mm low profile coronary angioplasty balloon catheters on 3.7–4.3 French shafts to reduce haemodynamic disturbance and ease the subsequent passage of the larger balloon catheters (fig 1A, B, and C). The details of this technique have been reported elsewhere in a different group of patients.⁹ In those undergoing dilatation in steps two balloons were used in one patient, three balloons in two, and four balloons in one patient. The final balloon diameters used ranged from 9 to

10 mm and the balloon to annulus ratios achieved ranged from 1.0 to 1.77.

STATISTICAL ANALYSIS

Data are presented as mean values (1 SD). Differences between variables before and after balloon dilatation were assessed by Student's *t* test for paired data.

Results

BALLOON DILATATION

The pulmonary valve was successfully dilated in 11 patients. In three patients with dysplastic valves, one of whom also had Ebstein's anomaly, the valve could not be crossed. Though the valve was crossed in another patient, the guide wire could not be passed to a stable position in either the left or right pulmonary arteries and thus the valve could not be dilated. All four of these patients had surgical valvotomy.

HAEMODYNAMIC RESULTS

The table summarises the haemodynamic changes. There was a significant decrease in right ventricular pressure, in the right ventricular to systemic pressure ratio, and in the transvalvar systolic gradients after balloon dilatation.

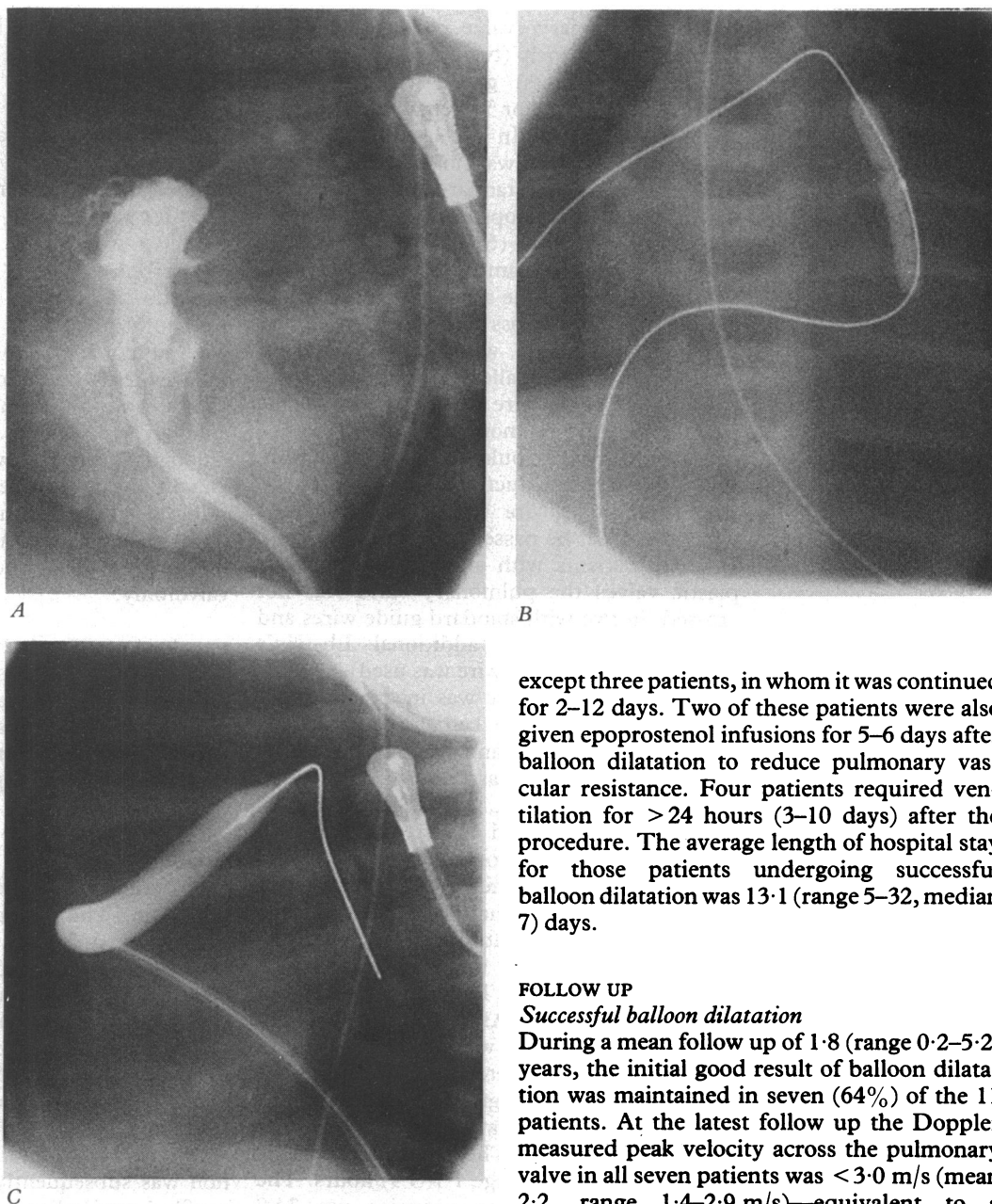
COMPLICATIONS

One patient (7%) died 7 days after balloon dilatation. There were no late deaths. This patient, aged 3 days, had severe pulmonary stenosis and duct-dependent pulmonary circulation. When the pulmonary valve was crossed with the guide wire and catheter and the catheter was placed in the descending aorta through the arterial duct severe hypotension and hypoxia developed which required removal of the catheter, cardiopulmonary resuscitation, and inotropes. Successful dilatation was subsequently performed with a low profile 5 mm balloon, but when we attempted to pass a larger balloon the iliac vein was dissected causing a large retroperitoneal haematoma. Though initially the patient was haemodynamically stable after the dilatation, with a Doppler estimated residual pulmonary gradient <16 mm Hg, epileptic seizures developed and ultrasound examination showed multiple intracerebral haemorrhages. He became neurologically unresponsive and died 7 days after balloon dilatation.

Minor immediate complications included transient bradycardia and hypotension on balloon inflation in all the patients. After successful dilatation of the pulmonary valve in one patient it proved difficult to withdraw the balloon catheter from the groin. On removal of the catheter a ring of vascular tissue was found wrapped around the mid-portion of the balloon. Contrast injection into the femoral vein showed a patent but irregular lumen with no extravasation of contrast material. The leg showed considerable venous congestion immediately after the procedure which resolved completely over 48 hours.

The long flexible tip of a "super-floppy"

Figure 1 (A) Right ventricular angiogram (left lateral projection) showing a tiny jet of contrast across stenosed pulmonary valve. (B) Still frame (anteroposterior projection) showing guide wire in distal right pulmonary artery and 3 mm coronary angioplasty balloon inflated across the pulmonary valve. "Waisting" of the balloon by the stenosed valve is visible. (C) Still frame (left lateral projection) showing 9 mm balloon fully inflated across the pulmonary valve. The waist on the balloon has disappeared.



0.018 inch guide wire fractured outside the groin in one patient. We salvaged this procedure by passing a short 18 gauge cannula over the broken end and replacing the guide wire. In two patients femoroiliac venous occlusion, which prevented femoral venous access, was found at subsequent repeat cardiac catheterisation.

TREATMENT AFTER DILATATION AND LENGTH OF HOSPITAL STAY

We were able to stop infusion of prostaglandin E_2 within 24 hours of balloon dilatation in all

except three patients, in whom it was continued for 2–12 days. Two of these patients were also given epoprostenol infusions for 5–6 days after balloon dilatation to reduce pulmonary vascular resistance. Four patients required ventilation for >24 hours (3–10 days) after the procedure. The average length of hospital stay for those patients undergoing successful balloon dilatation was 13.1 (range 5–32, median 7) days.

FOLLOW UP

Successful balloon dilatation

During a mean follow up of 1.8 (range 0.2–5.2) years, the initial good result of balloon dilatation was maintained in seven (64%) of the 11 patients. At the latest follow up the Doppler measured peak velocity across the pulmonary valve in all seven patients was <3.0 m/s (mean 2.2, range 1.4–2.9 m/s)—equivalent to a gradient of <36 mm Hg (figs 2 and 3). One critically ill neonate underwent preliminary dilatation with a 3 mm balloon and dilatation was electively repeated 3 weeks later with a 8 mm balloon (the outcome was a balloon/annulus ratio of 1.44). There has been no sign of recurrence in this patient; the Doppler estimated pulmonary valve pressure gradient was 16 mm Hg 1.6 years after initial dilatation.

In three (27%) patients stenosis recurred 4–9 months after the initial procedure. The mean pressure gradient at recurrence was 64 (range 55–73) mm Hg. In two of these patients further balloon dilatation was not possible because of femoroiliac venous thrombosis. All three had open pulmonary valvotomy and two of these required a transannular patch.

Effect of balloon size on late results

In those seven patients with a persisting good result after balloon dilatation the mean balloon/annulus ratio was 1.2 (range 0.95–1.77). Of these, two patients had a balloon/annulus ratio of 0.95 and 0.96. The mean balloon/annulus ratio at dilatation in the four patients requiring

Haemodynamic changes (mean (1 SD); range in parentheses) after balloon dilatation

	Before balloon dilatation	After balloon dilatation	p value*
RV pressure (mm Hg)	108.4 (22.7) (70–140)	63.9 (23.9) (37–125)	<0.0005
RV/systemic ratio (mm Hg)	1.4 (0.32) (1.1–2.1)	0.84 (0.24) (0.5–1.25)	<0.001
Transvalvar gradient (mm Hg)	81.4 (29.7) (20–120)	32.7 (27.7) (10–95)	<0.0005

*Paired t test. RV, right ventricular.

further treatment was 0.83 (range 0.6–1.1) and in only one of them was this ratio > 1.0 .

Initial surgical valvotomies

In four patients initial balloon dilatation was not possible. In three the valve was not crossed by a catheter or guide wire and in one the guide wire could not be positioned in a satisfactory and stable way. All underwent surgical valvotomy, three closed and one open with a transannular patch. During a follow up of 2.3 (range 0.8–5.3) years, two of the three patients who had a closed pulmonary valvotomy required a subsequent open valvotomy with enlargement of the outflow tract by a transannular patch and the third patient had balloon dilatation for recurrent stenosis. At the latest follow up the peak velocity into the pulmonary artery measured by Doppler ranged from 1.0 to 3.2 (mean 2.2) m/s.

Discussion

Critical pulmonary stenosis is often lethal in neonates, but if it presents in infants aged > 1 month the outcome is better. Urgent relief of obstruction is generally accepted as the appropriate treatment in neonates.¹⁰ Various surgical techniques including transarterial or transventricular pulmonary valvotomy or valvectomy, with either inflow occlusion or cardiopulmonary bypass, or a systemic-to-pulmonary artery shunt combined with a pulmonary valvotomy have been used. The surgical treatment, however, has been associated with an operative mortality of between 33% and 75%.^{11 12}

Perioperative infusion of prostaglandin E₁ may improve the outcome after surgical operation.¹² However, in the presence of a

hypoplastic right ventricle and raised pulmonary vascular resistance, the postoperative course can be variable. Even after successful surgery and survival, reoperations on the right ventricular outflow tract may be required. The 5 and 10 year actuarial results for freedom from reoperation in the survivors of surgical valvotomy in the neonatal period were 73% and 42% respectively; the patients often required a further pulmonary valvotomy or insertion of a transannular patch.¹² Effective non-surgical treatment of this condition therefore offers an attractive alternative.

Balloon dilatation of the pulmonary valve may provide effective relief of pulmonary valve stenosis of all degrees of severity and many studies have confirmed its safety and efficacy in infants and children.^{2-4 13 14} Good intermediate and long term results can be obtained with few reported complications related to the technique itself.^{15 16}

The results of successful balloon dilatation in a small number of neonates with critical stenosis of the pulmonary valve were reported as early as 1984.^{3 17} Subsequently Zeevi *et al* reported acceptable results of this treatment in six neonates⁸ and Rey *et al* in eight neonates.⁷ In the latter series there was one death unrelated to the procedure and two patients required repeat dilatation after the initial balloon dilatation.⁷ Our series analysed on an "intention-to-treat" basis consists of 15 unselected consecutive neonates presenting with critical stenosis of the pulmonary valve and intact ventricular septum since November 1983. The

Figure 2 Changes in transvalvar systolic pressure gradients after balloon dilatation. ○, continued good result; ●, re-stenosis requiring further treatment; * severe pulmonary stenosis with suprasystemic right ventricular pressure (the gradient was low because of large ductus arteriosus and high pulmonary vascular resistance).

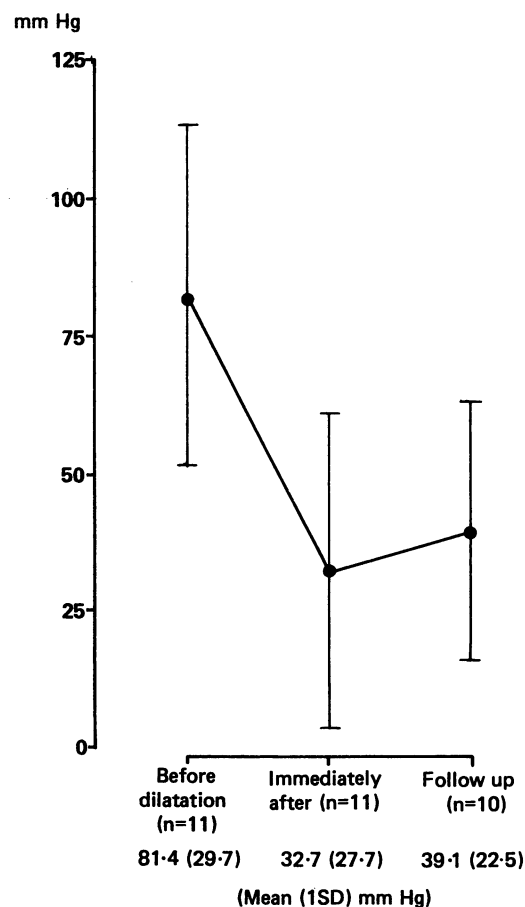
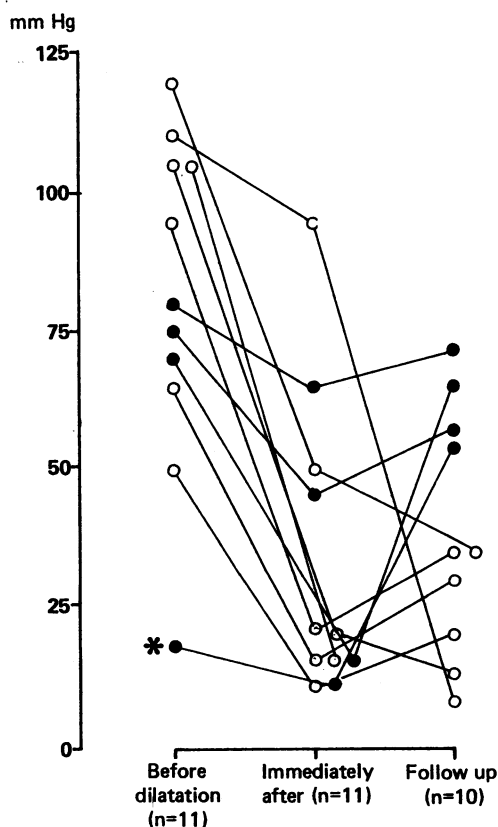


Figure 3 Changes in mean transvalvar systolic pressure gradient after balloon dilatation.

results show that balloon dilatation is an effective form of emergency treatment.

Balloon dilatation in neonates is often a technically difficult procedure but is associated with fewer risks than surgical operation. Several modifications in the technique are needed to reduce the occurrence of complications. Before balloon dilatation, prostaglandin E_2 infusion is maintained and the patient is stabilised haemodynamically (if necessary inotropes are also used). Goodale-Lubin and other end hole 4 or 5 French catheters are used to attempt to cross the pulmonary valve. This is often the most difficult part of the procedure. We now routinely attempt to cross the valve with "super-floppy" or "steerable" guide wires of 0.014, 0.018, or 0.020 inch diameter (Schneider-Shiley). These reduce the risk of infundibular trauma and can reduce the time needed to cross the valve. Since "steerable" guide wires became available we have failed to cross the valve in only one of the last nine patients. This patient had additional Ebstein's anomaly. Occasionally it is difficult to position the guide wire in either of the branch pulmonary arteries. Then the wire is passed through the ductus arteriosus and positioned in the descending aorta. The use of the ductus arteriosus may compromise pulmonary blood flow and result in haemodynamic deterioration; therefore speedy initial dilatation is essential. If the 5 French end hole catheter cannot be passed easily across the valve, then a coronary angioplasty balloon catheter of 3–3.5 mm diameter and 3.7 French shaft is used for the initial dilatation. This is followed by stepwise dilatation with larger balloon catheters to achieve the required balloon size.⁹

After dilatation the patient is weaned from the ventilator and prostaglandin E_2 while the arterial oxygen saturation is monitored. When desaturation persists and the right ventricular cavity is small prostaglandin E_2 infusion is continued for several days. Occasionally we have also used epoprostenol infusion to reduce the pulmonary vascular resistance. None of our patients required a systemic-to-pulmonary artery shunt.

In previous studies a dysplastic valve was regarded as a contraindication to balloon dilatation.^{2,13,18} Most stenotic pulmonary valves in the neonate, however, seem dysplastic on echocardiography and angiography. They range from thin mobile leaflets with "pure" commissural fusion to valves with mixed dysplasia and commissural fusion and to the severely dysplastic valve with thickened valve leaflets attached to a hypoplastic "ring" showing little expansion in systole.¹⁹ It is the degree of commissural fusion that probably determines the response to balloon dilatation, because disruption of commissural fusion by the balloon is thought to be the mechanism of relief of the obstruction.²⁰ One study has suggested that the degree of commissural fusion can be assessed from echocardiographic and angiographic appearances.²¹ In neonates with critical stenosis of the pulmonary valve we do not believe that this can be determined with confidence. In this situation, where any reduc-

tion in pulmonary valve gradient and improvement of pulmonary flow is valuable, we have performed balloon dilatation irrespective of the angiographic appearances, recognising that surgery may eventually be necessary.

Complications such as iliofemoral venous occlusion may prevent repeat balloon dilatation. We now routinely give heparin (50 U/kg) to patients before balloon dilatation. This and the use of balloons on smaller French size shafts may reduce venous occlusion.

All the procedures lasted 2–4 hours and the fluoroscopy time ranged from 25 to 57 minutes. A similar period of fluoroscopy (30–68 minutes) was reported by Zeevi *et al.*⁸ The duration of fluoroscopy is a potential risk to these babies because the dose of radiation received during the long screening times required for successful dilatation is not known. Fletcher *et al* calculated the radiation doses received by neonates during routine radiography and estimated the risks of malignant disease from fluoroscopy in different situations.²² The risk of malignant disease was thought to be as high as 1 in 150 for some routine catheterisations compared with 1 in 280 000 for a single chest or abdominal radiograph. This is an overestimate of the risks of catheterisation because it was assumed that the risks for limited body exposures were the same as for whole body exposures. Nevertheless, the actual dose received by the neonates should be measured by skin dose meters. This may be an important factor to consider in the risk-benefit equation when balloon dilatation is compared with surgical valvotomy.

Although good initial results in infants can be obtained with balloons that are undersized in relation to the pulmonary annulus, the incidence of restenosis is high.²³ Our series confirms this in the neonate also. Restenosis requiring further treatment developed in 60% of the patients with balloon/annulus ratios < 1.0 and in 14% in whom the balloon/annulus ratio was > 1.0. As in older children balloon/annulus ratios of > 1.2 give more satisfactory results.^{5,23} To achieve such ratios safely, we recommend progressive balloon dilatation to reduce the incidence of haemodynamic complications.⁹

While large balloon/annulus ratios are aimed for, too large a balloon/annulus ratio may be associated with complications. Ring *et al* showed that when balloons > 150% of the annulus size were used in newborn lambs there was an increased incidence of subendocardial haemorrhage affecting the right ventricular free wall and outflow tract caused by trauma from the proximal end of the balloon straightening against the curvature of the outflow tract.²⁴ In clinical studies of older children Radtke *et al* showed that balloons 30%–60% bigger than the annulus size could be used safely to produce greater reductions in gradient than those associated with smaller balloons.⁵ Furthermore, the frequency of recurrence of pulmonary valve stenosis requiring further treatment was higher for balloon/annulus ratios < 1.2 than for ratios > 1.2.²³ No benefit

in terms of an immediate reduction in gradient or frequency of recurrence of stenosis was shown for ratios > 1.5 .

We believe that balloon dilatation, rather than valvotomy, is the best treatment for neonatal critical pulmonary stenosis. It may be associated with a lower morbidity and mortality than surgical treatment. Restenosis may occur and is related to the use of undersized balloons. Other risks—for example the radiation dose of fluoroscopy—and the long term results when large balloon/annulus ratios are used, need further evaluation.

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